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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,421	12/08/2003	Henry Nita	PAT-1540	2510

7590 05/18/2006
Raymond Sun
12420 Woodhall Way
Tustin, CA 92782

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,421

Applicant(s)

NITA ET AL.

Examiner

Peter J. Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-8-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The action is final. New art is presented as necessitated by the Amendment dated 2-16-06.

Claims 17-29 are pending.

Claims 1-16 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, figure 1, and figure 4 all appear to include idiomatic errors. Claim 17 includes a guide catheter as described in the specification as element 36. However, figures 4b-e, which appears to be the claimed invention do not depict element 36. This creates ambiguity coupled with the inconsistency in figure 1, described below.

Figure 1 depicts a concentrically layered medical device. Looking at the shaft, beginning at the center and moving outward are elements 30,10,34,36. However, the proximal portion of the device (split between proximal and distal is the break) depicts that element 34 (or whatever the element resting longitudinally between 34 and 36) is the outermost element of the shaft, where element 36 has a smaller cross section.

Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-21, 23-25 and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaer et al. (6,522,930).

Independent claim 17

Schaer discloses a method of placing the distal end of an ultrasound (col. 2:46-51) catheter at a desired location inside a vessel, comprising:

providing a sheath (124, figures 14-15) having an elongate body that has a lumen and a distal end;

providing a guidewire (col. 12:55-61);

extending the ultrasound (col. 2:46-51) catheter (130) over the guidewire (col. 12:55-61) through the lumen of the sheath (124); and

extending the sheath (124) through the lumen of a guide catheter (col. 4:20-31).

Dependent claims (below numbers correspond to claims)

18 and 19. The method of claim 17, further including: advancing and retracting the sheath (124) independently beyond the distal end of the ultrasound catheter (130).

These steps are depicted in time sequential figures 14 and 15.

20. The method of claim 17, further including: torquing (see double-sided arrow at the distal end of the sheath in figure 15) the sheath to redirect the angled distal end of the sheath.

21. The patented sheath (124) includes an outer polymeric material (multiple tubings, col. 25:52) with a reinforcing layer (laminated braided structure, col. 25:53-55).

23. The distal shaft member (134, figure 15) has a smaller outer diameter than the main shaft member.

25. Excluding the porous membrane 132 in element 124 of figures 14 and 15, the drawings depict uniformity strongly inferring that the distal shaft member 134 is of equal hardness to 124 (the main body of the sheath).

27. Element 124 (distal end, figure 15) is angled within the claimed dimensions.

28. Element 124 shows angling in figure 15 inferring flexibility in the distal shaft member.

29. Figures 14 and 15 depict a plurality of members attached together (128,129,126,124).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer in view of Kesten (6,251,104).

Schaer is silent regarding lubricious coatings.

In an analogous device, Kesten discloses an elongate body (14/26; figure 2) with lubricious coatings. Lubricious coatings 27 and 30 both lie in *inner* surfaces of elements 14 and 13. According to MPEP 2144.04 VI. A, which is presented below, the reversal is obvious. Note also that the reversal here yields the same ends/result, to lubricate/facilitate movement of the two parts providing the motivation to combine the patents.

VI. REVERSAL, DUPLICATION, OR REAR-RANGEMENT OF PARTS

A. Reversal of Parts

In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient.).

Response to Arguments

Applicant's arguments with respect to claims 17-29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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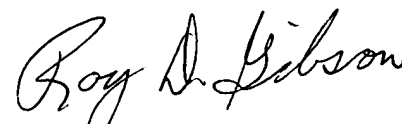
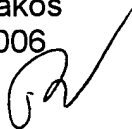
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
May 10, 2006



ROY D. GIBSON
PRIMARY EXAMINER